Department of Health and Human Services (HHS) — Prerule Stage
Food and Drug Administration (FDA)

1008. NATURAL RUBBER-CONTAINING DRUGS; USER LABELING

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 321; 21 USC 374; 21 USC 379; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 264; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 358; 21 USC 360; 21 USC 371

CFR Citation: 21 CFR 201

Legal Deadline: None

Abstract: The advance notice of proposed rulemaking requests comments on requirements under consideration for labeling statements on products regulated as drugs (including combination products regulated under drug labeling provisions) that contain natural rubber that contacts humans.

Timetable:

Action	Date	FR Cite
ANPRM	04/00/02	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Carol Drew, Regulatory Counsel, Office of Regulatory Policy, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
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RIN: 0910–AB56

1009. ● REQUIREMENTS FOR SUBMISSION OF IN VIVO BIOEQUIVALENCE DATA

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 355a; 21 USC 356; 21 USC 356a; 21 USC 356b; 21 USC 356c; 21 USC 371; 21 USC 374; 21 USC 379

CFR Citation: 21 CFR 314.96(a)(1); 21 CFR 314.94(a)(7); 21 CFR 320.21(b)(1)

Legal Deadline: None

Abstract: The Food and Drug Administration (FDA) is proposing to amend its regulations on submission of bioequivalence (BE) data to require an abbreviated new drug application (ANDA) applicant to submit data from all BE studies the applicant conducts on a drug product formulation submitted for approval. In the past, ANDA applicants have submitted BE studies demonstrating that a generic product meets BE criteria for FDA to approve the ANDA but have not typically submitted additional BE studies conducted on the same drug product formulation. FDA is proposing to require ANDA applicants to submit information, in either a complete or summary report, from all additional passing and nonpassing BE studies conducted on the same drug product formulation submitted for approval.

Timetable:

Action	Date	FR Cite
ANPRM	02/00/02	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Aida L. Sanchez, Special Assistant to the Director, Department of Health and Human Services, Food and Drug Administration, HFD-650, Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857
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RIN: 0910–AC23

1010. ● REQUIREMENTS FOR MEDICAL GAS CONTAINERS AND CLOSURE SYSTEMS

Priority: Substantive, Nonsignificant

Legal Authority: Not Yet Determined

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: The proposed rule would revise Food and Drug Administration regulations to require that medical gas manufacturers configure medical gas containers and closure systems, and provide training to personnel, to help avoid the risk of administration of the improper gas to patients.

Timetable:

Action	Date	FR Cite
ANPRM	02/00/02	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

Federalism: Undetermined

Agency Contact: Lee D. Korb, Regulatory Counsel, Office of Regulatory Policy, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 1451 Rockville Pike, Rockville, MD 20852
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RIN: 0910–AC24

Department of Health and Human Services (HHS) — Proposed Rule Stage
Food and Drug Administration (FDA)

1011. OVER-THE-COUNTER (OTC) DRUG REVIEW

Priority: Routine and Frequent

Legal Authority: 21 USC 321p; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 360a; 21 USC 371a; 21 USC 331; 21 USC 360; 21 USC 360b; 21 USC 361; 21 USC 371

CFR Citation: 21 CFR 310; 21 CFR 340; 21 CFR 341; 21 CFR 342; 21 CFR 343; 21 CFR 344; 21 CFR 345; 21 CFR 330; 21 CFR 333; 21 CFR 334; 21 CFR 335; 21 CFR 336; 21 CFR 337; 21 CFR 338; 21 CFR 339

Legal Deadline: None

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. NOTE: NPRM for ''Antidotes, Toxic Ingestion Products'' was combined with NPRM for ''Emetic

Products'' and reproposed as ''Poison Treatment Products.'' NPRM for ''Astringent (Wet Dressings) Products'' was included in the NPRM for ''Skin Protectant Products.'' NPRM for ''Diaper Rash Products'' was included in NPRMs for ''Antifungal,'' ''Antimicrobial,'' ''External Analgesic'' and ''Skin Protectant Products.'' NPRM for ''Fever Blister/Cold Sore Products (External)'' was included in NPRMs for ''External Analgesic'' and ''Skin Protectant Products.'' NPRM for ''Insect Bites and Stings (Relief) Products'' was included in NPRMs for ''External Analgesic'' and ''Skin Protectant Products.'' ''Poison Ivy/Oak/Sumac Prevention'' was included in NPRMs for ''External Analgesic'' and ''Skin Protectant Products.'' NPRM for ''Mercurial (Topical) Products'' was included in revised NPRM for ''Antimicrobial Products.'' NPRM for ''Alcohol (Topical) Products'' was included in revised NPRM for ''Antimicrobial Products.'' The NPRM for ''Antimicrobial Products'' was updated and split into two sections: First Aid Products and Health Care Antiseptic Products.

SMALL ENTITIES AFFECTED: The effects, if any, vary depending on the individual rulemaking. However, the Agency anticipates that the rules would not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act.

Timetable:

Acne (Topical) Products
- ANPRM 03/23/82 (47 FR 12430)
- NPRM 01/15/85 (50 FR 2172)
- NPRM (Amendment) 08/07/91 (56 FR 37622)
- Final Action 08/16/91 (56 FR 41008)

Alcohol (Oral) in OTC Drug Products
- NPRM 10/21/93 (58 FR 54466)
- Final Action 03/13/95 (60 FR 13590)
- NPRM (Amendment) 05/10/96 (61 FR 21392)
- Final Action (Amendment) 11/18/96 (61 FR 58629)

Anorectal Products
- ANPRM 05/27/80 (45 FR 35576)
- NPRM 08/15/88 (53 FR 30756)
- Final Action 08/03/90 (55 FR 31776)
- Final Action (LYCD) 09/02/93 (58 FR 46746)
- Final Action (Witch Hazel) 06/03/94 (59 FR 28766)

Antacid Drug Products
- ANPRM 04/05/73 (38 FR 8714)
- NPRM 11/12/73 (38 FR 31260)
- Final Action 06/04/74 (39 FR 9862)
- NPRM (Amendment) (Overindulgence) 12/24/91 (56 FR 66754)
- Final Action (Amendment) (Warning) 08/26/93 (58 FR 45204)
- NPRM (Amendment) (Testing) 09/23/93 (58 FR 49826)
- NPRM (Amendment)(Sodium Bicarb.) 02/02/94 (59 FR 5060)
- Final Action (Technical Amendment) 11/25/94 (59 FR 60555)
- Final Action (Amendment) (Testing) 02/08/96 (61 FR 4822)
- Final Action (Amendment)(Sodium B.) 12/00/02
- Final Action (Amendment) (Overindulgence) 12/00/02

Anthelmintic Products
- ANPRM 09/09/80 (45 FR 59541)
- NPRM 08/24/82 (47 FR 37062)
- Final Action 08/01/86 (51 FR 27756)

Antibiotic First Aid Products
- ANPRM 04/01/77 (42 FR 17642)
- NPRM 07/09/82 (47 FR 29986)
- Final Action 12/11/87 (52 FR 47312)
- NPRM (Amendment) 08/18/89 (54 FR 34188)
- Final Action 03/15/90 (55 FR 9721)
- NPRM (Amendment) 05/11/90 (55 FR 19868)
- NPRM (Amendment) 06/08/90 (55 FR 23450)
- Final Action (Amendment) 10/03/90 (55 FR 40379)
- Final Action (Amendment) 12/05/90 (55 FR 50171)
- NPRM (Amendment) (Warning) 02/14/96 (61 FR 5918)
- Final Action (Amendment)(Warning) 11/15/96 (61 FR 58471)

Anticaries Products
- ANPRM 03/28/80 (45 FR 20666)
- NPRM 09/30/85 (50 FR 39854)
- NPRM 06/15/88 (53 FR 22430)
- Final Action 10/06/95 (60 FR 52474)
- Final Action (Technical Amendment) 10/07/96 (61 FR 52285)

Antidiarrheal Products
- ANPRM 03/21/75 (40 FR 12924)
- NPRM 04/30/86 (51 FR 16138)
- NPRM (Amendment)(Trav. Diar.) 04/00/02
- Final Action 04/00/02

Antidotes, Toxic Ingestion Prdts (New Poison Treatment Prdts)
- ANPRM 01/05/82 (47 FR 444)

Antiemetic Products
- ANPRM 03/21/75 (40 FR 12934)
- NPRM 07/13/79 (44 FR 41064)
- Final Action 04/30/87 (52 FR 15886)
- NPRM (Amendment) 08/26/93 (58 FR 45216)
- Final Action 04/11/94 (59 FR 16981)
- NPRM (Amendment)(Warning) 08/29/97 (62 FR 45767)
- Final Action (Amendment) (Warning) 03/00/02

Antiflatulent Drug Products
- NPRM 11/12/73 (38 FR 31260)
- Final Action 06/04/74 (39 FR 19877)
- NPRM (Amendment) 01/29/88 (53 FR 2716)
- Final Action (Amendment) 03/05/96 (61 FR 8836)

Antifungal (Topical) Products
- ANPRM 03/23/82 (47 FR 12480)
- NPRM 12/12/89 (54 FR 51136)
- NPRM (Amendment) (Diaper Rash) 06/20/90 (55 FR 25240)
- Final Action (Amdt.)(Diaper Rash) 12/18/92 (57 FR 60430)
- Final Action (Partial) 09/02/93 (58 FR 46744)
- Final Action 09/23/93 (58 FR 49890)
- NPRM (Amendment) (Indications) 07/22/99 (64 FR 39452)
- Final Action 08/29/00 (65 FR 52302)
- NPRM (Amendment) Clotrimazole 05/29/01 (66 FR 29059)
- Final Action Clotrimazole 04/00/02

Antimicrobial Products
- ANPRM 09/13/74 (39 FR 33103)
- NPRM 01/06/78 (43 FR 1210)
- NPRM (Amendment) (Diaper Rash) 06/20/90 (55 FR 25246)
- Final Action (Diaper Rash) 03/00/04

Antiperspirant Products
- ANPRM 10/10/78 (43 FR 46694)
- NPRM 08/20/82 (47 FR 36492)
- Final Action 09/00/02

Aphrodisiac Products
- ANPRM 10/01/82 (47 FR 43572)
- NPRM 01/15/85 (50 FR 2168)
- Final Action 07/07/89 (54 FR 28780)

Astringent (Wet Dressings) Prdts (Merged w/other rulemkg)
- ANPRM 09/07/82 (47 FR 39436)

Benign Prostatic Hypertrophy Products
- ANPRM 10/01/82 (47 FR 43566)
- NPRM 02/20/87 (52 FR 5406)
- Final Action 02/27/90 (55 FR 6926)

Boil Ointments
- ANPRM 06/29/82 (47 FR 28306)
- NPRM 01/26/88 (53 FR 2198)
- Final Action 11/15/93 (58 FR 60332)

Camphorated Oil Drug Products
- ANPRM 09/26/80 (45 FR 63869)
- Final Action 09/21/82 (47 FR 41716)

Cholecystokinetic Products
- ANPRM 02/12/80 (45 FR 9286)
- NPRM 08/24/82 (47 FR 37068)
- Final Action 06/10/83 (48 FR 27004)
- NPRM (Amendment) 08/15/88 (53 FR 30786)
- Final Action (Amendment) 02/28/89 (54 FR 8320)

Corn and Callus Remover Products
- ANPRM 01/05/82 (47 FR 522)
- NPRM 02/20/87 (52 FR 5412)
- Final Action 08/14/90 (55 FR 33258)

Cough/Cold (Anticholinergic) Products
- ANPRM 09/09/76 (41 FR 38312)
- NPRM 07/09/82 (47 FR 30002)
- Final Action 11/08/85 (50 FR 46582)

Cough/Cold (Antihistamine) Products
ANPRM 09/09/76 (41 FR 38312)
NPRM 01/15/85 (50 FR 2200)
NPRM (Amendment) 08/24/87 (52 FR 31892)
Final Action 12/09/92 (57 FR 58356)
Final Action (Amendment)(Warning) 01/28/94 (59 FR 4216)
NPRM (Amendment)(Warning) 08/29/97 (62 FR 45767)
Reopen Record (Common Cold) 08/25/00 (65 FR 51780)
Final Action (Amendment)(Warning) 03/00/02
Final Action 12/00/02

Cough/Cold (Antitussive) Products
ANPRM 09/09/76 (41 FR 38312)
NPRM 10/19/83 (48 FR 48576)
Final Action 08/12/87 (52 FR 30042)
NPRM (Amendment) (Warning) 07/06/89 (54 FR 28442)
NPRM (Amendment) 10/02/89 (54 FR 40412)
Final Action (Amendment) (Warning) 07/06/90 (55 FR 27806)
Final Action (Amendment) 10/03/90 (55 FR 40381)
NPRM (Amendment)(Warning) 06/19/92 (57 FR 27666)
NPRM (Amendment)(Ingredients) 12/09/92 (57 FR 58378)
Final Action (Amendment)(Warning) 10/20/93 (58 FR 54232)
Final Action (Amdt.)(Ingredients) 06/03/94 (59 FR 29172)
NPRM (Amendment)(Warning) 08/29/97 (62 FR 45767)
NPRM (Amendment)(Flammability) 07/20/98 (63 FR 38762)
Final Action (Amendment)(Flammability) 08/01/00 (65 FR 46864)
Final Action (Amendment)(Warning) 03/00/02

Cough/Cold (Bronchodilator) Products
ANPRM 09/09/76 (41 FR 38312)
NPRM 10/26/82 (47 FR 47520)
Final Action 10/02/86 (51 FR 35326)
NPRM (Amendment)(Warning) 06/19/92 (57 FR 27662)
Final Action (Amendment)(Warning) 10/20/93 (58 FR 54238)
NPRM (Amendment)(MDI) 03/09/95 (60 FR 13014)
NPRM (Amendment)(Ephedrine) 07/27/95 (60 FR 38643)
Final Action (Amendment) (MDI) 05/20/96 (61 FR 25142)
Final Action (Amendment) (Ephedrine) 12/00/02

Cough/Cold (Combination) Products
ANPRM 09/09/76 (41 FR 38312)
NPRM 08/12/88 (53 FR 30522)
NPRM (Amendment)(DPH Combinations) 02/23/95 (60 FR 10286)
Final Action (Theophylline) 07/27/95 (60 FR 38636)
Final Action 09/00/02
NPRM (Amendment) (Ephedrine Combo) 12/00/02

Cough/Cold (Diphenhydramine) Products
Final Action/Enforcement Policy 04/09/96 (61 FR 15700)

Cough/Cold (Expectorant) Products
ANPRM 09/09/76 (41 FR 38312)
NPRM 07/09/82 (47 FR 30002)
Final Action 02/28/89 (54 FR 8494)
Final Action (Technical Changes) 06/30/92 (57 FR 29176)

Cough/Cold (Expectorant/Ipecac) Products
ANPRM 09/09/76 (41 FR 38312)
NPRM 07/09/82 (47 FR 30002)
Final Action 09/14/92 (57 FR 41857)

Cough/Cold (Nasal Decongestant) Products
ANPRM 09/09/76 (41 FR 38312)
NPRM 01/15/85 (50 FR 2220)
NPRM (Amendment) 06/19/92 (57 FR 27658)
Final Action 08/23/94 (59 FR 43386)
Final Action; Partial Stay 03/08/96 (61 FR 9570)
Final Action (Amendment)(Levmetamfetamine) 07/30/98 (63 FR 40647)
NPRM (Phenylpropanolamine) 04/00/02

Dandruff, Seborrheic Dermatitis and Psoriasis Control Products
ANPRM 12/03/82 (47 FR 54646)
NPRM 07/30/86 (51 FR 27346)
Final Action 12/04/91 (56 FR 63554)
NPRM (Amendment) 04/05/93 (58 FR 17554)
Final Action 01/28/94 (59 FR 4000)

Daytime Sedatives
ANPRM 12/08/75 (40 FR 57292)
NPRM 06/13/78 (43 FR 25544)
Final Action 06/22/79 (44 FR 36378)

Diaper Rash Products (Merged w/other rulemkg)
ANPRM 09/07/82 (47 FR 39406)

Digestive Aid Products
ANPRM 01/05/82 (47 FR 454)
NPRM 01/29/88 (53 FR 2706)
Final Action 10/21/93 (58 FR 54450)

Eligibility Criteria for Additional Conditions
ANPRM 10/03/96 (61 FR 51625)
NPRM 12/20/99 (64 FR 71062)
Final Action 04/00/02

Emetic Products
ANPRM 03/21/75 (40 FR 12939)
NPRM 09/05/78 (43 FR 39544)

Exocrine Pancreatic Insufficiency Products
ANPRM 12/21/79 (44 FR 75666)
NPRM 11/08/85 (50 FR 46594)
NPRM (Reproposed) 07/15/91 (56 FR 32282)
Final Action 04/24/95 (60 FR 20162)

External Analgesic Products
ANPRM 12/04/79 (44 FR 69768)
NPRM 02/08/83 (48 FR 5852)
NPRM (Amendment) (Dandruff) 07/30/86 (51 FR 27360)
NPRM (Amendment) (Anorectal) 08/25/88 (53 FR 32592)
NPRM (Amendment) (Poison Ivy) 10/03/89 (54 FR 40818)
NPRM (Amendment) (Fvr Blister/Ext) 01/31/90 (55 FR 3370)
NPRM (Amendment) (1%Hydrocortisone) 02/27/90 (55 FR 6932)
NPRM (Amendment) (Diaper Rash) 06/20/90 (55 FR 25234)
Final Action (Diaper Rash) 12/18/92 (57 FR 60426)
NPRM (Amendment)(Warning) 08/29/97 (62 FR 45767)
Final Action (Amendment)(Warning) 03/00/02

Fever Blister Products (Internal)
ANPRM 01/05/82 (47 FR 502)
NPRM 06/17/85 (50 FR 25156)
Final Action 06/30/92 (57 FR 29166)

First Aid Antiseptic
ANPRM 09/13/74 (39 FR 33103)
NPRM 01/06/78 (43 FR 1210)
NPRM (Revised) 07/22/91 (56 FR 33644)

Fvr Blister/Cold Sore Prdts (Ext.) (To be merged w/other rulemkg)
ANPRM 09/07/82 (47 FR 39436)

Hair Grower and Hair Loss Prevention Products
ANPRM 11/07/80 (45 FR 73955)
NPRM 01/15/85 (50 FR 2190)
Final Action 07/07/89 (54 FR 28772)

Healthcare Antiseptic Products
ANPRM 09/13/74 (39 FR 33103)
NPRM 01/06/78 (43 FR 1210)
NPRM (Revised) 06/17/94 (59 FR 31402)
Final Action 12/00/02

Hormone (Topical) Products
ANPRM 01/05/82 (47 FR 430)
NPRM 10/02/89 (54 FR 40618)
Final Action 09/09/93 (58 FR 57608)

Hypo/Hyperphosphatemia Products
ANPRM 12/09/80 (45 FR 81154)
NPRM 01/15/85 (50 FR 2160)
Final Action 05/11/90 (55 FR 19852)

Ingrown Toenail Relief Products
ANPRM 10/17/80 (45 FR 69128)
NPRM 09/03/82 (47 FR 39120)
Final Action 09/09/93 (58 FR 47602)
NPRM 03/00/02

Insect Bite & Sting (Relief) Prdts (Merged w/other rulemkg)
ANPRM 09/07/82 (47 FR 39412)

Insect Repellent Drug Products (Internal)
ANPRM 01/05/82 (47 FR 424)
NPRM 06/10/83 (48 FR 26986)
Final Action 06/17/85 (50 FR 25170)

Internal Analgesic Products
ANPRM 07/08/77 (42 FR 35346)
NPRM 11/16/88 (53 FR 46204)
NPRM (Amendment) (Overindulgence) 12/24/91 (56 FR 66762)
NPRM 10/20/93 (58 FR 54224)
NPRM (Amendment)(Sodium Bicarbonate) 02/02/94 (59 FR 5068)
NPRM (Prof. Labeling)(Acute MI) 06/13/96 (61 FR 30002)
NPRM (Amendment)(Alcohol Warning) 11/14/97 (62 FR 61041)
Final Action (Alcohol Warning) 10/23/98 (63 FR 56789)
Final Action (Aspirin Prof. Label) 10/23/98 (63 FR 56802)
NPRM (Amendment)(Ibuprofen) 04/00/02
Final Action 12/00/02
Final Action (Sodium Bicarbonate) 12/00/02
Final Action (Amendment)(Overindulgence) 12/00/02

Internal Deodorant Products
ANPRM 01/05/82 (47 FR 512)
NPRM 06/17/85 (50 FR 25162)
Final Action 05/11/90 (55 FR 19862)

Labeling of Drug Products for OTC Human Use
NPRM (Sodium Labeling) 04/25/91 (56 FR 19222)
NPRM 04/05/93 (58 FR 17553)
Final Action 01/28/94 (59 FR 3998)
NPRM (Do not mix drugs) 08/03/94 (59 FR 39499)
NPRM (Amendment) (Do not mix drugs) 10/04/95 (60 FR 52058)
NPRM (Unless a doctor tells you) 03/04/96 (61 FR 8450)
Final Action (Sodium Labeling) 04/22/96 (61 FR 17798)
NPRM (Calcium/Magnesium/Potassium) 04/22/96 (61 FR 17807)
Withdrawal (Unless a doctor tells you) 02/27/97 (62 FR 9024)
Final Action (Format/Examples) 03/17/99 (64 FR 13254)
Final Action (Technical Amendment) 01/03/00 (65 FR 7)
Final Action (Ca/Mg/K/Na) 12/00/01

Laxative Products
ANPRM 03/21/75 (40 FR 12902)
NPRM 01/15/85 (50 FR 2124)
NPRM (Amendment) (Directions/Bulk) 10/01/86 (51 FR 35136)
NPRM (Amendment) (Docusate Salts) 09/02/93 (58 FR 46589)
NPRM (Amendment)(Sodium Phosphates) 03/31/94 (59 FR 15139)
NPRM (Phenolphthalein) 09/02/97 (62 FR 46223)
Final Action (Sodium Phosphates) 05/21/98 (63 FR 27836)
NPRM (Amendment)(Phosphates Label) 05/21/98 (63 FR 27886)
NPRM (Amendment)(Stim. Laxative) 06/19/98 (63 FR 33592)
Final Action; stay (Na Phos. Enema) 12/07/98 (63 FR 67399)
Part. With. (Na Phos. Prof. Lab.) 12/09/98 (63 FR 67817)
Final Action (Phenolphthalein) 01/29/99 (64 FR 4535)
Final Action 12/00/02
Final Action (Stim. Laxative) 12/00/03

Leg Muscle Cramps (Nocturnal Relief) Products
ANPRM 10/01/82 (47 FR 43562)
NPRM 11/08/85 (50 FR 46588)
Final Action 08/22/94 (59 FR 43234)

Male Genital Desensitizer Products
ANPRM 09/07/82 (47 FR 39412)
NPRM 10/02/85 (50 FR 40260)
Final Action 06/19/92 (57 FR 27654)

Menstrual Products
ANPRM 12/07/82 (47 FR 55075)
NPRM 11/16/88 (53 FR 46194)
Final Action 12/00/02

Mercurial (Topical) Products (To be merged w/other rulemkg)
ANPRM 01/05/82 (47 FR 436)

NDA Labeling Exclusivity (Merged with other rulemaking)
NPRM 11/09/93 (58 FR 59622)

Nailbiting/Thumbsucking Deterrent Products
ANPRM 10/17/80 (45 FR 69122)
NPRM 09/03/82 (47 FR 39096)
Final Action 09/02/93 (58 FR 46749)

Nighttime Sleep Aid Products
ANPRM 12/08/75 (40 FR 57292)
NPRM 06/13/78 (43 FR 25544)
Final Action 02/14/89 (54 FR 6814)
NPRM (Amendment) 08/26/93 (58 FR 45217)
Final Action (Amendment) 04/11/94 (59 FR 16982)
NPRM (Amendment)(Warning) 08/29/97 (62 FR 45767)
Final Action (Amendment)(Warning) 03/00/02

Ophthalmic Products
ANPRM 05/06/80 (45 FR 30002)
NPRM 06/28/83 (48 FR 29788)
Final Action 03/04/88 (53 FR 7076)
Final Action (Anti-infective) 12/18/92 (57 FR 60416)
NPRM (Amendment) (Warning) 02/23/98 (63 FR 8888)
Final Action 06/21/00 (65 FR 38426)

Oral Discomfort (Relief) Products
ANPRM 05/25/82 (47 FR 22712)
NPRM 09/24/91 (56 FR 48302)
Final Action 06/00/03

Oral Health Care Products
ANPRM 05/25/82 (47 FR 22760)
NPRM 01/27/88 (53 FR 2436)
NPRM (Amendment) (Antimicrobials) 02/09/94 (59 FR 6084)
ANPRM (Plaque/Gingivitis) 06/00/02

Oral Wound Healing Products
ANPRM 11/02/79 (44 FR 63270)
NPRM 07/26/83 (48 FR 33984)
Final Action 07/18/86 (51 FR 26112)

Otic Products (Dry Water-Clogged Ears)
NPRM (Amendment) 08/17/99 (64 FR 44671)
Final Action 08/10/00 (65 FR 48902)

Otic Products (Earwax)
NPRM 07/09/82 (47 FR 30012)
Final Action 08/08/86 (51 FR 28656)

Otic Products (Swimmers Ear)
NPRM 07/30/86 (51 FR 27366)
Final Action 02/15/95 (60 FR 8916)
Final Action Partial Stay 08/16/95 (60 FR 42435)

Overindulgence Remedies
ANPRM 10/01/82 (47 FR 43540)
NPRM 12/24/91 (56 FR 66742)
Final Action 12/00/02

Overindulgence Remedies/Prevention of Inebriation
ANPRM 10/01/82 (47 FR 43540)
Final Action 07/19/83 (48 FR 32872)

Pediculicide Products
ANPRM 06/29/82 (47 FR 28312)
NPRM 04/03/89 (54 FR 13480)
Final Action 12/14/93 (58 FR 65452)
NPRM (Labeling Amendment) 04/00/02

Phenylpropanolamine Products (Labeling)
NPRM 02/14/96 (61 FR 3912)

Poison Ivy/Oak/Sumac Prevention (Merged w/other rulemkg)
ANPRM 09/07/82 (47 FR 39412)

Poison Treatment Products
NPRM 01/15/85 (50 FR 2244)
Final Action 12/00/02
NPRM (Amendment) 12/00/02

Quinine for Malaria
NPRM 04/19/95 (60 FR 19650)
Final Action 03/20/98 (63 FR 13526)

Salicylate (Reye Syndrome)
NPRM (Amendment)(Warning) 05/05/93 (58 FR 26886)
ANPRM 10/20/93 (58 FR 54228)
Final Action (Warning) 04/00/02

Skin Bleaching Products
ANPRM 11/03/78 (43 FR 51546)
NPRM 09/03/82 (47 FR 39108)
NPRM (Reproposed) 01/00/03

Skin Protectant Products
ANPRM 08/04/78 (43 FR 34628)
NPRM 02/15/83 (48 FR 6820)
NPRM (Amendment) (Astringent) 04/03/89 (54 FR 13490)
NPRM (Amendment) (Poison Ivy) 10/03/89 (54 FR 40808)
NPRM (Amendment) (Fvr Blister/Ext) 01/31/90 (55 FR 3362)
NPRM (Amendment) (Diaper Rash) 06/20/90 (55 FR 25204)
Final Action (Astringent) 10/21/93 (58 FR 54466)
Final Action (Witch Hazel) 06/03/94 (59 FR 28767)
Final Action (Poison Ivy) 11/00/01
Final Action 11/00/01
Final Action (Astringent) 12/00/01
Smoking Deterrent Products
ANPRM 01/05/82 (47 FR 490)
NPRM 07/03/85 (50 FR 27552)
Final Action 06/01/93 (58 FR 31236)
Status of Certain Category II and III Ingredients
NPRM 05/16/90 (55 FR 20434)
Final Action 11/07/90 (55 FR 46914)
NPRM 08/25/92 (57 FR 38568)
Final Action 05/10/93 (58 FR 27636)
Final Action 04/22/98 (63 FR 19799)
Final Action 08/24/98 (63 FR 44996)
Final Action 09/27/01 (66 FR 49276)
Final Action 12/00/01
Stimulant (Overindulgence) Products
NPRM (Amendment) 12/24/91 (56 FR 66758)
Final Action 12/00/02
Stimulant Products
ANPRM 12/08/75 (40 FR 57292)
NPRM 06/13/78 (43 FR 25544)
Final Action 02/29/88 (53 FR 6100)
Stomach Acidifier Products
ANPRM 10/19/79 (44 FR 60316)
NPRM 01/15/85 (50 FR 2184)
Final Action 08/17/88 (53 FR 31270)
Sunscreen Products
ANPRM 08/25/78 (43 FR 38206)
NPRM 05/12/93 (58 FR 28194)
NPRM (Amendment) 06/08/94 (59 FR 29706)
NPRM (Amendment)(Avobenzone) 09/16/96 (61 FR 48645)
Final Action (Avobenzone Enf. Pol.) 04/30/97 (62 FR 23350)
Final Action 05/21/99 (64 FR 27666)
ANPRM (and Insect Repellant) 12/00/01
NPRM (UVA/UVB) 06/00/02
Sweet Spirits of Nitre
ANPRM 02/22/80 (45 FR 11846)
Final Action 06/27/80 (45 FR 43400)
Topical Drug Products Containing Benzoyl Peroxide (Labeling)
NPRM 02/17/95 (60 FR 9554)
Final Action 12/00/02
Vaginal Contraceptive Products
ANPRM 12/12/80 (45 FR 82014)
NPRM 02/03/95 (60 FR 6892)
NPRM (Amendment) 06/00/02
Vaginal Drug Products
ANPRM 10/13/83 (48 FR 46694)
Withdrawal 02/03/95 (60 FR 5226)
NPRM (Douches) 12/00/02
Vitamin/Mineral Products
ANPRM 03/16/79 (44 FR 16126)
Withdrawal 11/27/81 (46 FR 57914)
Wart Remover Products
ANPRM 10/03/80 (45 FR 65609)
NPRM 09/03/82 (47 FR 39102)
NPRM (Amendment) 03/27/87 (52 FR 9992)
Final Action 08/14/90 (55 FR 33246)
NPRM (Amendment)(Directions) 01/28/94 (59 FR 4015)
Final Action (Amdt.)(Directions) 11/23/94 (59 FR 60315)
Water Soluble Gums
NPRM 10/30/90 (55 FR 45782)
Final Action 08/26/93 (58 FR 45194)
NPRM 12/00/02
Weight Control Products
ANPRM 02/26/82 (47 FR 8466)
NPRM 10/30/90 (55 FR 45788)
Final Action 08/08/91 (56 FR 37792)
NPRM (Phenylpropanolamine) 04/00/02

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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RIN: 0910–AA01

1012. ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR DRUGS AND BIOLOGICS

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 360; 21 USC 360b; 21 USC 371; 21 USC 374; 42 USC 262

CFR Citation: 21 CFR 201; 21 CFR 207; 21 CFR 314

Legal Deadline: None

Abstract: The proposed rule would amend FDA regulations on the registration of producers of drugs and the listing of drugs in commercial distribution. The proposed revisions would reorganize, consolidate, clarify, and modify current regulations concerning who must register establishments and list drug or biological products. The proposal describes when, how, and where to register and list and what information must be submitted for registration and listing. The proposed regulations would also require the electronic submission of most registration and listing information.

Timetable:

Action	Date	FR Cite
NPRM	04/00/02	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

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RIN: 0910–AA49

1013. INVESTIGATIONAL NEW DRUGS: EXPORT REQUIREMENTS FOR UNAPPROVED NEW DRUG PRODUCTS

Priority: Routine and Frequent

Legal Authority: 21 USC 321; 21 USC 381; 21 USC 382; 21 USC 393; 42 USC 241; 42 USC 243; 42 USC 262; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 371

CFR Citation: 21 CFR 312.110

Legal Deadline: None

Abstract: The proposed rule would amend the regulations on the exportation of unapproved new drug products, including biological products, for investigational use. In general, the proposed rule would provide four different routes for exporting an unapproved new drug product for investigational use. One route would permit exportation, if the drug is the subject of an investigational new drug application (IND) and is being exported for use in the investigation. A second route would permit exportation, without prior Food and Drug Administration (FDA) approval and without an IND, if the product is to be exported for use in a clinical investigation and has received marketing authorization in certain developed countries. The third route